3 month progress summary: Wahl, RL Analysis of SARC 11 Trial PET Data by PERCIST with Linkage to Clinical Outcomes

Primary goals and objectives:

To analyze quantitatively and qualitatively the FDG PET data prospectively obtained at up to three time points in the SARC 11 trial (311 patients accrued). The analyses will focus on linkage of PET findings to clinical outcomes of response, PFS and survival. Specific metrics to be assessed include:

a) PERCIST criteria response
b) EORTC criteria response
c) Analysis using glycolytic volumes (TLG and TV)
d) Qualitative assessments of response by three readers
e) Linkage of these values to clinical outcomes
Deliverables:
a) Transfer of image data set to JHU IRAT servers
b) Quality analysis of PET data for compliance with PERCIST standards
c) Normal tissue quality assessments
d) Visual analysis of PET data
e) Quantitative analysis of PET data
f) Linkage of results to clinical outcomes
g)Manuscript (s) of results for publication and support of FDA qualification

These include linkage of PET changes in SUV to response

Timeline [must include intermediate measureable milestones.]

Months 0-3: Transfer of data sets to JHU and assessment of quality
Months 3-6: Visual analysis of PET data
Months 6-10: Quantitative assessment of PET data
Months 10-12: Statistical analysis of data including linkage to outcomes and preparation of final reports. Includes precision analysis of both the Visual and Quantitative data assessed by the 3 readers.

Our 0-3 month progress has been to transfer two sets of the SARC data to JHU and to examine its quality. We have begun on the visual and quantitative analysis, as well. Not unexpectedly, some issues of quality of the entire data set arose. In addition, we have worked on refining an automated quantitative assessment tool. Details follow:

A disk with 318 subject folders was received in the IRAT laboratory at Johns Hopkins. Initial analysis concluded that all the PET studies had been converted into a non-standard file format (BIT format), which had stripped the image data of the information necessary to perform a quantitative analysis (image units, injected dose, etc.). We requested the PET data in its original format on March 10, 2011, and received a disk with data on June 1, 2011. This new dataset contained 306 subject folders with PET imaging data of which 64 cases have been disqualified from further analysis for either: 1) not being able to be transformed into image units of SUV-lbm, or 2) containing only a single time point of data (i.e. lacking follow-up data). Thus, 242 patient studies will be used in the PERCIST analysis.

The PERCIST analysis is being performed through the use of a semi-automated analysis system developed in-house at Johns Hopkins. This system collects the following information from each analysis run and exports it into a relational database for subsequent analysis and future data-mining:

Patient Level (Subject ID)
- Study Level (Date, Description, Inj. Activity, Weight, Height, Sex, Camera, Software Ver.)
  - Series Level (Time, Description, Duration of Uptake, Image Format)
    - Analysis Level (Date/Time, Units of Analysis, Auto-Analysis parameters)
      - Assessable Disease Level (Label, Quantitative Imaging Statistics)

These data allow each imaging study to be analyzed for internal quality control (uptake duration, liver value, etc., all within reasonable limits). It also allows for the monitoring and measurement of key parameters for quality control across time points (consistency in inj. activity, liver value, camera/software stability between scans, etc.). Unfortunately, the data has been stripped of information pertaining to collimation (2D or 3D) or reconstruction algorithm, so those quality control parameters are unavailable in this analysis. Reports of these assessments have been developed and can now be automatically generated by the system as data is entered into the underlying database.

Auto-PERCIST assessment analysis reports are currently being developed which will capture key disease object parameters from each baseline to follow-up study pairing.

To date, five patient studies have been analyzed with this system. As much of the infrastructure and preliminary work leading up to the actual image data analysis is now complete, it is expected that the rate of data acquisition will increase accordingly.

Example reports illustrating key technical and liver quality control parameters are provided.